Translation

PCT/JP2003/014101

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 3116WO0P	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/JP2003/014101	International filing date (*day/month/year*) 05 November 2003 (05.11.2003)	Priority date (*day/month/year*) 06 November 2002 (06.11.2002)

International Patent Classification (IPC) or national classification and IPC
A61K 31/4468, 31/454, 31/4545, A61P 1/04, 1/14, 3/10, 9/06, 9/10, 9/12, 11/00, 11/06, 13/12, 15/12, 19/02, 25/04, 29/00, 37/04, 43/00, C07D 211/58, 211/66, 401/04, 401/06

Applicant
TAKEDA CHEMICAL INDUSTRIES, LTD.

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
04 December 2003 (04.12.2003)	08 July 2004 (08.07.2004)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP2003/014101

I. Basis of the report

1. With regard to the **elements** of the international application:*

☒ the international application as originally filed

☐ the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the claims:

pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the drawings:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP03/14101

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 9

because:

☒ the said international application, or the said claims Nos. 9 relate to the following subject matter which does not require an international preliminary examination *(specify)*:

The subject matter of claim 9 relates to a method for treatment of the human body by therapy.

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 9.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP03/14101

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	19, 23, 26-28	YES
	Claims	1-8, 10-18, 20-22, 24, 25	NO
Inventive step (IS)	Claims		YES
	Claims	1-8, 10-28	NO
Industrial applicability (IA)	Claims	1-8, 10-28	YES
	Claims		NO

2. Citations and explanations

Document 1: US, 4126689, A
Document 2: US, 4791120, A
Document 3: US, 4801615, A
Document 4: J. Med. Chem., 1989, Vol. 32, No. 12, pages 2534-2542

Claims 1-8 and 10

Document 1 (Table 1) describes compounds having an antiarrhythmic effect. In this case, the 8th compound of Table 1 corresponds to a compound of formula (I") of the present application. Furthermore, since the "neuromedine U receptor regulators" of the present application are applied to the therapy of arrhythmia, the "neuromedine U receptor regulators" of the present application are identical with the medicines described in document 1 in active ingredient and diseases covered.

Therefore, the subject matters of claims 1-8 and 10 do not appear to be novel or to involve an inventive step in view of document 1.

Claims 11-28

Documents 2 and 3 respectively describe compounds used for medicines and also describe compounds similar to the compounds described in claim 11 of the present application. So, a person skilled in the art could have easily variously changed the combinations of substituent groups in the chemical structural formulae stated in documents 2 and 3, for obtaining compounds optimum or suitable as medicines.

The compounds 7d, e, g, h, i and k stated in document 4 correspond to the compounds of the formula (I'''') of the present application.

Therefore, the subject matters of claims 11-18, 20-22, 24 and 25 do not appear to be novel or to involve an inventive step in view of document 4, and the subject matters of claims 11-28 do not appear to involve an inventive step in view of documents 2 or 3.

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 1 relates to neuromedine U receptor regulators containing any one of the compounds having the partial structure represented by formula (A) or any one of their salts as an active ingredient.

In this case, the compounds having the partial structure represented by formula (A) include very numerous compounds, but the compounds supported in the sense of PCT Article 6 and disclosed in the sense of PCT Article 5 are only very few of the claimed compounds.

Therefore, the IPER covers the portions supported and disclosed by the specification, i.e., neuromedine U receptor regulators containing any one of the compounds represented by formula (I'''') or any one of their salts.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of : IPC

Int.Cl^{7} C07D417/04,417/14,409/14